

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	
)	
Chin Ying HSIAO et al.)	Group Art Unit: 1653
)	
Application No.: 10/822,938)	Examiner: S. M. Noakes
)	
Filed: April 12, 2004)	Confirmation No. 4416
)	
For: NOVEL COLLAGEN)	
PRODUCTION METHOD)	

Commissioner for Patents
Washington, DC 20231

Sir:

DECLARATION UNDER 37 C.F.R. § 1.132

I, Seah June Nam, Ph.D., do hereby make the following declaration:

1. I am an inventor of the subject matter of this application and am employed as the Chief Scientific Officer with EcoDynamic BioLab.

2. I received my Masters of Science in 1994 from Yang Ming Medical University, Graduate School of Microbiology and Immunology. In 2002, I completed a doctorate in microbiology and immunology at the National University of Singapore, Temasek Life Sciences Laboratory. I have published several peer-reviewed journal articles in the area of microbiology. A copy of my curriculum vitae is attached as Exhibit A to this declaration.

3. My duties at EcoDynamic BioLab include the development of methods to isolate collagen for therapeutic purposes. I am familiar with methods for the isolation of

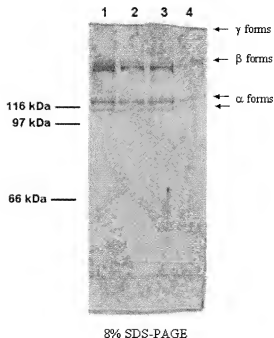
collagen and have attempted to isolate collagen from various collagen-containing tissues.

4. I have reviewed the pending claims and specification of this application, which clearly details the isolation of collagen monomers from various tissue sources using microbial fermentation.

5. I have read and am familiar with the Office's rejection of claims 54-78 for lack of enablement, as set forth in the Advisory Action of May 22, 2007, the Office Action of October 6, 2006, and the Office Action of April 20, 2006.

6. My own research at EcoDynamic BioLab in this area demonstrates that the invention is enabled. The methodology detailed in Example 3 of the specification (pp. 21-22) was used to isolate collagen monomers from porcine tissue. Four different bacterial strains were tested: *Bacillus subtilis*, *Bacillus pumilus*, *Pseudomonas aeruginosa* (ATCC 27853), and *Escherichia coli* (ATCC 10798).

7. All four bacterial strains were effective in isolating collagen monomers, as evidenced by the SDS-PAGE gel in the figure below.

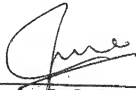


Lane 1 *Bacillus subtilis*
Lane 2 *Bacillus pumilus*
Lane 3 *Pseudomonas aeruginosa*
Lane 4 *Escherichia coli*

8. Based upon these data and my own experience and my study of the above, it is my belief and professional opinion that one of ordinary skill in the art could practice the claimed methods using the guidance provided in the specification. The five examples in the specification and the experiments detailed above demonstrate that undue experimentation would not be required to determine what species of microorganism will work with the claimed invention.

9. I hereby declare that the foregoing statements of fact set forth above are true, and that all opinions are believed to be true.

Dated: Nov. 5 - 2007

By: 
Dr. Seah June Nam